

CT imaging before transcatheter aortic valve implantation (TAVI) using variable helical pitch scanning and its diagnostic performance for coronary artery disease

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Abstract

Objectives To evaluate the effectiveness of CT before TAVI using variable helical pitch (VHP) scanning and its diagnostic performance for coronary artery disease (CAD).

Methods Sixty patients (84.4 ± 4.6 years) scheduled for TAVI underwent CT using VHP scanning with the contrast material (CM) volume calculated as scanning time × weight [kg] × 0.06 mL. Retrospective electrocardiography (ECG)-gated scanning was utilized to examine the thorax, and non-ECG-gated scanning of the abdomen immediately followed. We analyzed CT attenuation values of the coronary arteries, aorta, iliac and femoral arteries. The coronary CT angiography images were evaluated for the presence of stenosis (≥50 %); invasive coronary angiography served as a reference standard. **Results** The average attenuations of all of the arteries were greater than 400 HU. We could evaluate the peripheral access vessels and dimensions of the ascending aorta, aortic root, and aortic annulus in all patients. The average volume of CM was 38.7 ± 8.5 mL. On per-patient and vessel analysis, CT showed 91.7 % and 89.5 % sensitivity, and 91.3 % and 97.4 % negative predictive value (NPV).

Conclusions CT using VHP scanning with an average CM volume of 38.7 mL is useful before TAVI and had a high sensitivity and NPV in excluding obstructive CAD.

Key Points

- TAVI-planning CT using variable helical pitch (VHP) scanning is useful.
- The average volume of contrast material was 38.7 ± 8.5 mL.
- The average attenuations of all the arteries were >400 HU.
- This CT had a high sensitivity and NPV for excluding obstructive CAD.

Keywords Multidetector computed tomography · Contrast media · Sensitivity and specificity · Coronary artery disease · Transcatheter aortic valve replacement

Abbreviations

CAD	Coronary artery disease
CAG	Coronary angiography
CM	Contrast material
CT	Computed tomography
ECG	Electrocardiogram
NPV	Negative predictive value
PPV	Positive predictive value
TAVI	Transcatheter aortic valve implantation

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Introduction

Transcatheter aortic valve implantation (TAVI) has been increasingly common and accepted as an alternative to surgical aortic valve implantation in the elderly and high-risk patients [1–3].

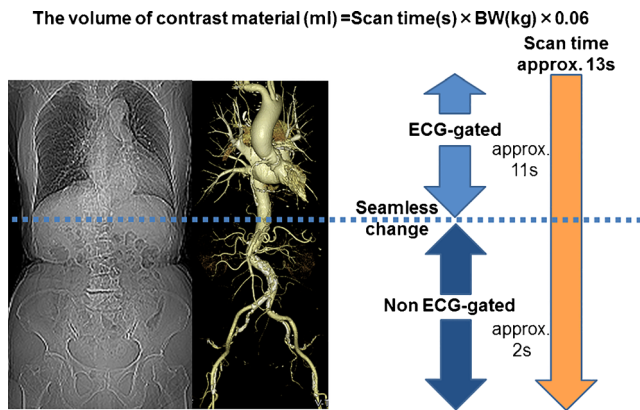


Fig. 1 Variable helical pitch scanning. Variable helical pitch scanning allows a seamless change of scan pitch during one continuous acquisition and enables a combination of gated and non-gated acquisitions within one scan

Computed tomography (CT) imaging before TAVI is necessary to evaluate the access route (transapical or transfemoral), aortic annular dimensions, aortic valve structure and calcifications [4]. We can also predict the orthogonal view on the aortic annular plane called the perpendicular view. CT protocols before TAVI vary and depend on the CT scanner. In the guidelines of CT imaging prior to TAVI [4], the aortic root must be imaged with electrocardiogram (ECG) gating to allow for motion-free imaging. However, it is not necessary to image the entire aorta and iliofemoral arteries in ECG gating. For these sections, non-gated acquisitions may be preferable because of lower radiation exposure and because of faster volume coverage that requires lower volumes of iodinated contrast material (CM). The volume of CM is of concern in many candidates for TAVI because the candidates frequently have impaired renal function [4]. Previous studies have reported that the chronic kidney disease

Table 1 Clinical and CT baseline characteristics ($n = 60$)

Demographic variables	Value Means ± standard deviation (range; median) or n (%)
Age (years)	84.4 ± 4.6 (72–94; 86)
Female/male, n (%)	43 (71.7)/17 (28.3)
Height (cm)	148.7 ± 8.3 (131–173; 147)
Weight (kg)	49.4 ± 10.2 (34–74; 47)
BMI (kg/m ²)	22.2 ± 3.6 (17–31; 21.8)
BSA (m ²)	1.41 ± 0.17 (1.14–1.84; 1.38)
Cr (mg/dl)	0.97 ± 0.34 (0.52–2.65; 0.86)
BNP (pg/ml)	364.5 ± 457.5 (16.3–2276.0; 208.2)
Post-PCI (stent), n (patient) (%), n (vessel) (%)	6 (10), 8 (3.3)
Post-CABG, n (patient) (%), n (vessel) (%)	2 (3.3), 5 (2.1)
Ca score*	1018.1 ± 1130.6 (0–4453; 648)
Ca score = 0, n (%)	4 (6.7)
0 < Ca score ≤ 400, n (%)	21 (35.0)
400 < Ca score, n (%)	34 (56.7)
HR (beats/min) on CT	70.9 ± 12.3 (48–109; 69)
CTDI vol (mGy) for CT	19.6 ± 3.0 (12.1–33.4; 19.9)
DLP (mGy · cm) for CT	1281.6 ± 195.7 (764.2–2086.5; 1275.9)
Scan length (mm) of CT	609.1 ± 44.1 (520.6–707.9; 606.7)
Mean mA on CT	343.0 ± 39.4 (224.8–560.6; 340.2)
Mean mAs on CT	94.3 ± 10.8 (61.8–154.2; 93.5)
Scan time (s) of CT	13.04 ± 0.99 (10.2–16.5; 12.92)
CM (ml) for CT	38.7 ± 8.5 (25.9–60.1; 36.5)
Injection rate (ml/s) of CM on CT	3.0 ± 0.6 (2.0–4.4; 2.8)
TAVI approach	
Transfemoral, n (%) / Transapical, n (%)	53 (88.3) / 7 (11.7)
TAVI procedure	
23 mm Sapien XT n (%) / 26 mm Sapien XT, n (%)	44 (77.3) / 16 (26.7)

BMI: body mass index BSA: body surface area, HR: heart rate, CABG: coronary artery bypass grafting, CTDI vol: CT dose index volume, DLP: dose length product, CM: contrast material

* $n = 59$: The Ca score for one patient was not measured, because of the lead metal artifact of the pace maker

(CKD) stage before TAVI affects the clinical outcome [5, 6]. Therefore, the volume of CM should be minimized as low as possible in CT imaging before TAVI.

Recently, a promising CT technique of variable helical pitch (VHP) scanning was introduced for clinical use. VHP scanning allows a seamless change of pitch during one continuous acquisition and enables the combination of ECG-gated and non-ECG-gated acquisitions within one scan. Due to the seamless change of pitch, reduction in CM is expected.

On another front, TAVI candidates are elderly and have a high prevalence of coronary artery disease (CAD) [7]. A high NPV (93.8 %) for excluding the obstructive CAD of TAVI candidates with dual-source CT system has been reported in a previous study [8]. If we also show a high NPV in CT imaging before TAVI using VHP scanning, the need for pre-procedural invasive coronary angiography (CAG) in patients who are CT negative for CAD may be reduced, and the total volumes of CM for such patients can be minimized. Furthermore, the overall cost for TAVI is still higher than that for surgical aortic valve replacement, and the high cost of care in TAVI patients is an increasing problem [9]. The reduction of invasive CAG as a negative result of TAVI planning CT can lead to a reduction of the total cost for TAVI.

The purpose of this study was to evaluate the effectiveness of CT before TAVI using VHP scanning and its diagnostic performance for CAD.

Materials and methods

Study population

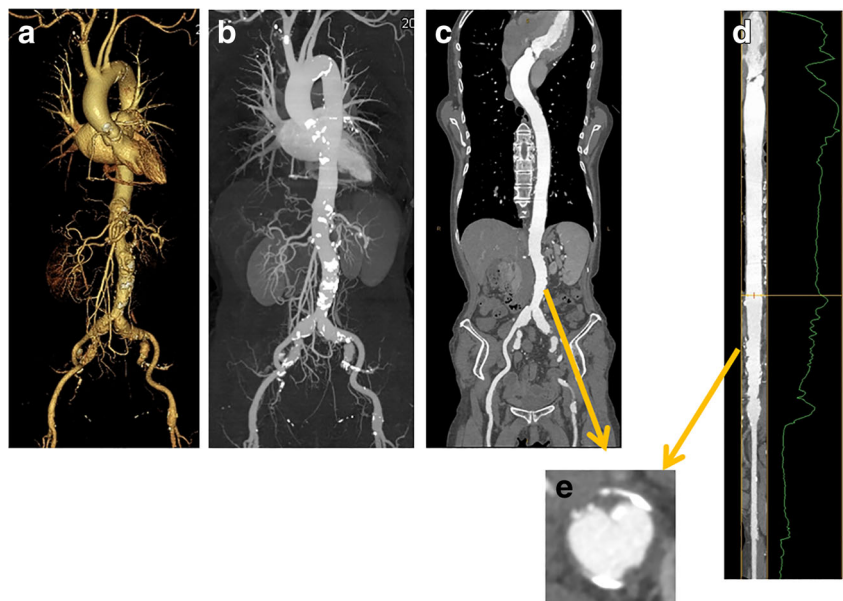
Ninety patients with severe symptomatic AS who were receiving TAVI planning CT and underwent TAVI

between April 4, 2014, and March 31, 2015, were considered for inclusion in this study. Patients were excluded if they were scanned with protocols that differed from the VHP scanning protocol described below ($n = 30$). Thus, a total of 60 patients were included in the final analysis. The patients comprised 17 men and 43 women with a mean age of 84.4 ± 4.6 years, a mean height of 148.7 ± 8.3 cm, a mean body weight of 49.4 ± 10.2 kg and a mean body mass index (BMI) of 22.2 ± 3.6 kg/m². The excluded patients comprised 8 men and 22 women with a mean age of 83.5 ± 4.3 years, a mean height of 147.2 ± 9.1 cm, a mean body weight of 48.6 ± 10.9 kg and a mean BMI of 22.3 ± 4.1 kg/m². Notably, there was no significant difference of the gender, age, height, weight, or BMI ($P = 0.8676, 0.2585, 0.6405, 0.8338, \text{ and } 0.7320$, respectively, using a chi-square test for gender and a Mann–Whitney U test for age, height, weight and BMI) between the included and excluded patients. All of the included patients underwent both CT and invasive CAG within 2 months before the TAVI procedure and underwent the TAVI procedure using a balloon-expandable Edwards SAPIEN XT heart valve (Edwards Lifesciences, Irvine, CA, USA). This study was approved by our institutional review board, and written informed consent was obtained from each participant.

CT protocol

All CT examinations were performed using a 320-detector row CT scanner (Aquilion ONE/ViSION Edition, Toshiba Medical Systems, Otawara, Japan). No premedication for heart rate control or vasodilatation was added for CT acquisition. CT examinations were performed using the

Fig. 2 A 76-year-old female TAVI candidate with a height of 151 cm, a body weight of 50 kg, and a body mass index of 21.9 kg/m². **A.** Volume-rendering image; **B.** Maximum intensity projection image; **C.** Curved planar reformation (CPR) image; **D.** Straightened CPR image; **E.** Cross-section image. The images were obtained using 40.5 ml of contrast materials



following parameters: peak tube voltage, 100 kV; tube current, 185–580 mA (determined based on a pre-specified BMI protocol); rotation speed, 0.275 s; and slice collimation, 0.5×100 mm. We used VHP scanning, which allows a seamless change in the scan pitch during one continuous acquisition and enables a combination of gated and non-gated acquisitions within one scan. A pitch of 0.15–0.17 was chosen for ECG-gated thoracic imaging depending on the patient's heart rate, and 0.87 was used for non ECG-gated abdominal scans. Retrospective ECG-gated scanning was utilized to examine the thorax and covered the structures from approximately 2 cm above the apex to the base of the heart. Non-ECG-gated scanning of the abdomen and pelvis (to the level of the proximal thigh) followed the thorax scan without delay (Fig. 1). A double-channel injection system (Dual Shot; Nemoto, Tokyo, Japan), equipped with a high-pressure-resistant extension tube (Injector tube; Top, Tokyo, Japan), a 22G indwelling needle (Supercath; Medikit, Tokyo, Japan) and right antecubital venous access were used. The volume of CM (Iopamiron 370 mg/mL iodine concentration; Bayer, Osaka, Japan: or 350 mg/mL) was determined by the scanning time (approximately 13 s, depending on the patient's habitus and heart rate) \times weight \times 0.06 mL. CM was injected at a rate of the weight \times 0.06 mL/s followed by 20 mL of the saline solution at a rate of the weight \times 0.06 mL/s. Scanning was automatically started with a 3-s delay after the attenuation of a region of interest (ROI) placed in the ascending

thoracic aorta reached the threshold of +150 Hounsfield units (HU).

Before contrast-enhanced CT scanning, all of the patients underwent unenhanced CT with prospective ECG gating for coronary artery calcium scoring.

Invasive CAG

Invasive CAG was performed by experienced cardiologists using standard techniques and the acquisition of standard projection planes. CAG images were classified into 16 segments according to the AHA classification. Stenosis severity was determined via clinical studies using quantitative coronary angiography. Greater than or equal to 50 % stenosis of each vessel was rated as positive.

Image analysis

Continuous 1-mm-thick CT images for the evaluation of the access route (from above the apex to the proximal thigh) were reconstructed using adaptive iterative dose reduction 3D (AIDR 3D) [10]. We analyzed CT attenuation values of the coronary arteries (the proximal portions of the left main trunk, left anterior descending artery, left circumflex branch and right coronary artery), aortic root, aortic arch, descending aorta, aorta at the diaphragm level, abdominal aorta at the renal artery level, aortic bifurcation, common iliac arteries, external iliac arteries and common femoral arteries.

Table 2 Average CT attenuation value of each artery

Vessel	CT attenuation (HU) Average \pm standard deviation (range)	Shapiro–Wilk test <i>P</i> value
LMT	471.2 \pm 88.6 (327.4–707.2)	0.154
LAD	448.0 \pm 88.4 (278.9–739.3)	0.107
LCx	442.3 \pm 83.2 (291.5–690.0)	0.006
RCA	445.9 \pm 90.7 (280.3–703.5)	0.115
Aortic root	500.9 \pm 102.1 (299.8–737.3)	0.287
Aortic arch	506.2 \pm 76.9 (338.0–690.9)	0.579
Descending aorta	500.9 \pm 82.3 (311.6–716.3)	0.669
Aorta at the diaphragm level	440.7 \pm 89.1 (277.3–648.6)	0.139
Abdominal aorta	422.9 \pm 89.5 (268.2–639.4)	0.165
Aortic bifurcation	449.1 \pm 87.4 (299.6–675.7)	0.447
Right CIA	433.3 \pm 76.1 (302.4–636.1)	0.277
Left CIA	430.8 \pm 75.5 (296.5–607.7)	0.295
Right EIA	420.1 \pm 74.4 (283.9–607.2)	0.613
Left EIA	421.6 \pm 73.1 (288.8–580.8)	0.213
Right CFA	432.4 \pm 73.7 (266.3–612.7)	0.912
Left CFA	430.8 \pm 76.2 (236.5–613.2)	0.823

LMT: left main trunk; LAD: left anterior descending artery; LCx: left circumflex branch; RCA: right coronary artery; CIA: common iliac artery; EIA: external iliac artery; CFA: common femoral artery

Table 3 Diagnostic performance of TAVI-planning CT for the detection of stenosis ≥ 50 %

	Sensitivity	Specificity	PPV	NPV	Accuracy
Per vessel	89.5 % (34/38)	75.2 % (152/202)	40.5 % (34/84)	97.4 % (152/156)	77.5 % (186/240)
Per patient	91.7 % (22/24)	58.3 % (21/36)	59.5 % (22/37)	91.3 % (21/23)	71.7 % (43/60)

PPV: positive predictive value; NPV: negative predictive value

For evaluation of the heart, 0.5-mm-thick CT images were reconstructed at 30 % (for aortic valve ring assessment), 45 % (end-systole), and 75 % (mid-diastolic) of the cardiac cycle. We did not use ECG editing. All coronary CT data were analyzed by two radiologists (with 5 and 3 years of experience in coronary CT angiographic imaging) in consensus for the presence and degree of stenosis for the left main trunk, left anterior descending artery, left circumflex branch and right coronary artery. Readers were blinded to the results of invasive CAG. Axial CT images and multi-planar reconstruction (MPR) images were used for coronary CT evaluation. The radiologists evaluated images for the presence of ≥ 50 % stenosis; invasive coronary angiography served as the reference standard. When a vessel was not evaluable because of motion artifacts (increased heart rate or arrhythmia, and incomplete breath holding) or heavy calcifications, it was classified as non-diagnostic and treated as positive for stenosis (≥ 50 %). We calculated the sensitivity, specificity, PPV and NPV for per vessel and per patient. We also calculated the diagnostic performance of TAVI-planning CT excluding non-diagnostic vessels resulting from heavy calcification and that of TAVI-planning CT excluding all non-diagnostic vessels. We assumed a high NPV (>90 %) for excluding significant coronary artery stenosis, consistent with a previous study [8].

The Agatston method for quantification of the coronary artery calcium level was used for the calculation of the coronary artery calcium scores on unenhanced CT [11].

Statistical analysis

The variables were expressed as the means \pm standard deviation (SD). The normality of the CT attenuation values was assessed using the Shapiro–Wilk test.

Table 4 Diagnostic performance of TAVI-planning CT for the detection of stenosis ≥ 50 % (excluding non-diagnostic vessels resulting from heavy calcification)

	Sensitivity	Specificity	PPV	NPV	Accuracy
Per vessel	89.2 % (33/37)	76.4 % (152/199)	41.3 % (33/80)	97.4 % (152/156)	78.4 % (185/236)
Per patient	91.3 % (21/23)	61.8 % (21/34)	61.8 % (21/34)	91.3 % (21/23)	73.4 % (42/57)

PPV: positive predictive value; NPV: negative predictive value

Results

The clinical and CT baseline characteristics are summarized in Table 1.

The average CT scanning time from above the apex to the proximal thigh was 13.04 ± 0.99 s (range: 10.2–16.5 s), and the average volume of CM was 38.7 ± 8.5 mL (range: 25.9–60.1 mL). There was no patient with contrast-induced acute kidney injury. The average attenuations of all of the arteries were more than 400 HU (Table 2). All of the minimum CT attenuations of the arteries were >236.5 HU. We could evaluate the peripheral access vessels and dimensions of the ascending aorta, aortic root, and aortic annulus in all of the patients (Fig. 2). The procedural success rate was 100 % (transfemoral in 53 cases; transapical in 7 cases).

Two hundred forty coronary vessels in 60 patients were analyzed for the evaluation of CAD. In invasive coronary angiography as the reference standard, 15.8 % (38/240) of the coronary vessels were positive (stenosis ≥ 50 %), and 40.0 % (24/60) of patients were positive. Eighteen vessels (7.5 %) in 13 patients were classified as non-diagnostic and treated as positive for stenosis (≥ 50 %; motion artifacts due to increased heartrate or arrhythmia; 9 vessels, 8 patients, motion artifacts due to incomplete breath holding; 5 vessels, 3 patients, heavy calcification; 4 vessels, 3patients). On per-patient analysis, TAVI-planning CT had a sensitivity of 91.7 %, a specificity of 58.3 %, a PPV of 59.5 %, and an NPV of 91.3 % (Table 3). On per-vessel analysis, TAVI-planning CT had a sensitivity of 89.5 %, a specificity of 75.2 %, a PPV of 40.5 %, and an NPV of 97.4 % (Table 3). The diagnostic performances of TAVI-planning CT excluding non-diagnostic vessels resulting from heavy calcification and that excluding all non-diagnostic vessels are shown in Tables 4 and 5, respectively. An example of a TAVI candidate is shown in Fig. 3. We misdiagnosed two vessels (#4AV and #9) as non-stenosis (<50 %;

Table 5 Diagnostic performance of TAVI-planning CT for the detection of stenosis ≥ 50 % (excluding all non-diagnostic vessels)

	Sensitivity	Specificity	PPV	NPV	Accuracy
Per vessel	88.6 % (31/35)	81.3 % (152/187)	47.0 % (31/66)	97.4 % (152/156)	82.4 % (183/222)
Per patient	88.2 % (15/17)	70.0 % (21/30)	62.5 % (15/24)	91.3 % (21/23)	76.6 % (36/47)

PPV: positive predictive value; NPV: negative predictive value

percutaneous coronary intervention [PCI] was not performed for these vessels).

The mean calcium score was 1018.1 ± 1130.6 . The mean CTDI volume was 19.6 ± 3.0 mGy, and the mean DLP was 1281.6 ± 195.7 mGy cm. The effective dose was estimated as 19.1 ± 2.9 mSv, determined using the DLP measurements and appropriate normalized coefficients reported in a previous study concerning trunk CT (0.015 mSv/(mGy cm)) [12].

Discussion

Our study showed that CT imaging before TAVI using VHP scanning with an average volume of CM (38.7 ± 8.5 mL) is useful for a TAVI procedure that is accurate and safe, maintaining all of the average CT attenuations of the coronary and access route arteries greater than 400 HU; there was no patient

with contrast-induced acute kidney injury after CT, and the procedural success rate was 100 %. In the previous study, the optimal vascular attenuation for stenosis detection in coronary CT angiography was thought to be approximately 350–400 HU [13, 14], and lower attenuation leads to the overestimation of stenosis [15]. Therefore, our study would have sufficiently good CT attenuation to evaluate all of the arteries. Two other previous studies have reported CT imaging before TAVI using dual-source CT systems with an average CM volume of 20 mL [16] and 40 mL [17]; however, to the best of our knowledge, this is the first detailed study conducted to demonstrate the usefulness of a single-source CT system using the VHP scan technique. Additionally, these two previous studies using dual-source CT systems did not refer to the diagnostic performance for obstructive CAD.

Our study revealed that TAVI-planning CT with VHP scanning had a high NPV for obstructive CAD. If we can exclude coronary artery stenosis by TAVI-planning CT and can avoid unnecessary invasive coronary angiography (23/60 [38 %] in the present study) in TAVI candidates, we could further reduce the total cost as well as the total volume of CM and radiation exposure. One previous study [8] has reported that TAVI-planning CT had a sensitivity of 98.6 %, a specificity of 55.6 %, a PPV of 85.7 %, and an NPV of 93.8 % on per-patient analysis for the evaluation of coronary artery stenosis, a finding that is almost equal to the values in our study, although the mean calcium scores in our study (1018.1) were numerically higher than those of this previous study (722). However, in the previous study, the total volume of CM was 60 mL (triphasic protocol: 40 mL of CM + 30 mL of 2:1 CM-to-saline mixture + 40 mL of saline chaser), and this value was greater than that in our study. We misdiagnosed two vessels (#4AV and #9) as non-stenosis (<50 %). However, PCI was not performed for these vessels. PCI for AS patients was usually performed only for severely stenotic lesions in proximal coronaries that subtend a large area of myocardium at risk [7]. Therefore, our misdiagnoses would not be so problematic.

The per vessel specificity, per patient specificity, per vessel PPV, and per patient PPV values in the present study were 75.2 %, 58.3 %, 40.5 %, and 59.5 %, respectively. Excluding vessels resulting from heavy calcification, the values were 76.4 %, 61.8 %, 41.3 %, and 61.8 %, respectively. In addition, excluding all non-diagnostic vessels (resulting from heavy calcification + motion artifacts), the values increased to 81.3 %, 70.0 %, 47.0 %, and 62.5 %. Therefore,

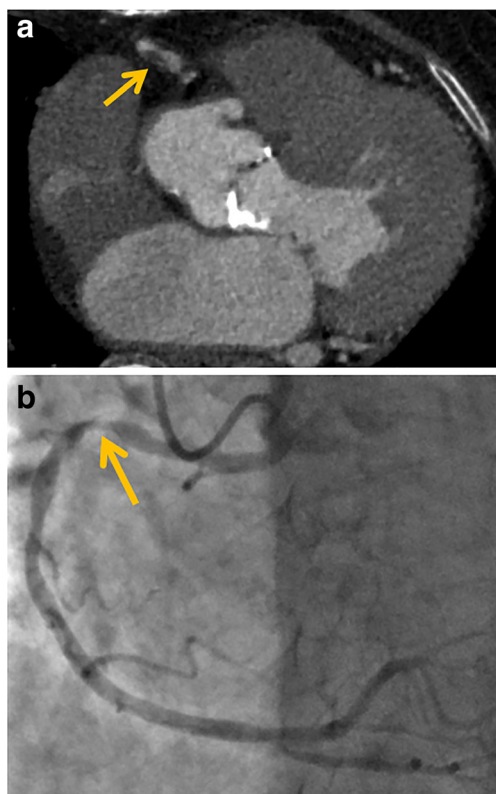


Fig. 3 An 86-year-old female TAVI candidate. A. Axial CT image. B. Invasive coronary angiography. CT image and invasive coronary angiography show 90 % stenosis in the right coronary artery (#1)

the lower specificity and PPV in our study would be due to not only heavy calcification but also motion artifacts (increased heart rate, arrhythmia and incomplete breath holding). The TAVI candidates were elderly, and several patients found it difficult to hold their breath. Furthermore, the heart rates of the AS patients were difficult to control, even using β -blocker.

Because retrospective ECG-gated scanning for thoracic imaging was utilized, the radiation dose of the CT protocol in our study was higher than that of previous studies using dual-source CT [16, 17] that did not evaluate coronary artery stenosis. In the SCCT guideline of TAVI-planning CT, imaging of the aortic root and annulus in systole is said to be preferable over diastole because of the dynamic changes of the annulus and slightly larger annular sizes noted in systole [18, 19]. On the other hand, coronary imaging in mid-diastole is considered to be preferable over systole except that motion artifact has occurred. Therefore, if we evaluate coronary arteries in TAVI CT, it is necessary to acquire both the systole and diastole phases. In addition, if retrospective ECG-gated scanning is utilized, we can analyze both systolic and diastolic coronary CT angiography images. Furthermore, given the common advantage of the age of the patients being considered for TAVI, radiation exposure may be a lesser concern.

A lower kV setting or low keV monochromatic image is also useful for reducing CM and yielding higher HUs during scanning in TAVI planning CT [20, 21]. However, a lower kV setting increases the image noise, and incidental findings might be overlooked. In a previous report, significant non-cardiac findings were commonly observed in patients referred to TAVI planning CT [22]. Therefore, we did not use 80 kVp but instead used a 100-kVp setting in the present study.

There are some limitations in our study. First, the prevalence of stenosis of coronary arteries in our study was 40 %, and the NPV of CT coronary angiograms might be changed according to the prevalence of the study population. However, the previous study reported that the prevalence of CAD in AS patients was 40–75 % [7], and the prevalence of CAD in our study was within the range. Second, we used a 320-detector-row CT scanner with VHP scanning, and the diagnostic performance in our study may not be generalizable to other acquisition protocols and CT systems. However, we used a single-source CT system; if it is possible to use a scan protocol similar to that of the VHP scan in our study (currently, there are no other vendors offering VHP scan mode.), our results could be generalizable to many other single-source CT systems.

Conclusion

CT imaging using VHP scanning is useful before TAVI with an average CM volume of 38.7 mL in the restricted cohort

examined in the present study, thus showing high sensitivity and NPV in excluding obstructive CAD.

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Institutional review board approval was obtained. Written informed consent was obtained from all patients in this study. No study subjects or cohorts have been previously reported. Methodology: retrospective, diagnostic or prognostic study, performed at one institution.

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